

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON

IN RE DIGITEK®

PRODUCT LIABILITY LITIGATION

MDL NO. 1968

THIS DOCUMENT RELATES TO ALL CASES

PRETRIAL ORDER # 52
(SELF-CRITICAL ANALYSIS PRIVILEGE)

Currently pending before the court are (1) Plaintiffs'¹ Motion for Leave to File Plaintiffs' Motion to Compel Documents and Deposition Testimony under seal, filed December 29, 2009 (docket # 265); and (2) Plaintiffs' Motion to Compel Documents and Deposition Testimony, filed December 29, 2009 (# 265-2). The Actavis Defendants have responded (# 273), and Plaintiffs have replied (# 282), making the matter ripe for determination.

Motion to Compel

1. Arguments of the Parties.

In their Motion to Compel, Plaintiffs seek an order compelling Actavis Totowa LLC, Actavis, Inc. and Actavis Elizabeth LLC (the "Actavis Defendants") to produce documents and testimony relating to their Good Manufacturing Practices ("GMP") compliance audits.

Briefly, on December 9, 2009, Plaintiffs took the deposition

¹ The Motion was filed by the Plaintiffs' Steering Committee.

of Actavis Totowa LLC's Director of Quality Assurance Operations, Paul Galea, who testified that he performed an audit of Actavis Totowa LLC in 2007, approximately one year before the Digitek® recall. According to Plaintiffs, "[t]he purpose of this audit was to determine whether Actavis Totowa LLC's manufacturing, packaging and testing operations were in compliance with GMP as set forth in Title 21 of the Code of Federal Regulations." (# 265-2, p. 1.) At deposition, counsel for the Actavis Defendants instructed Mr. Galea not to answer questions related to this audit based on the self-critical analysis privilege, and Mr. Galea complied. (# 265-2, p. 1.)

Plaintiffs assert that the self-critical analysis privilege should not be recognized in the present litigation because (1) the Actavis Defendants failed to assert the self-critical analysis privilege in response to Plaintiffs' requests for documents relating to audits or identify any such document in their Privilege Log, thereby waiving the privilege; (2) federal and state courts, including those in West Virginia, have repeatedly rejected the self-critical analysis privilege, particularly in connection with routine and voluntary safety audits; (3) the Actavis Defendants cannot meet the four pronged self-critical analysis privilege delineated in Bredice v. Doctors Hosp., Inc., 50 F.R.D. 249, 250 (D. D.C. 1970), aff'd, 479 F.2d 920 (Table) (D.C. Cir. 1973) and Dowling v. American Hawaii Cruises, Inc., 971 F.2d 423, 426 (9th

Cir. 1992); and (4) the documents and testimony relating to the GMP compliance audit are highly relevant to Plaintiffs' claims in this litigation, and Plaintiffs will be severely prejudiced if discovery of this information is denied. (# 265-2, p. 2.)

In response, the Actavis Defendants assert that Mr. Galea prepared an assessment report of Actavis Totowa operations to assist him in harmonizing the GMP aspect of the Actavis entities globally. The Actavis Defendants assert that Mr. Galea did not conduct a routine GMP compliance audit of Actavis Totowa operations. The Actavis Defendants further assert that they did not waive the self-critical analysis privilege and that Mr. Galea's work and report are the type that fall squarely within the self-critical analysis privilege as defined and applied "in this Circuit." (# 273, p. 2.) Finally, the Actavis Defendants assert that the report and testimony of Mr. Galea have nothing to do with Plaintiffs' theories of double-thick Digitek® tablets and the recall or inconsistent (high and low) digoxin dosages in distributed Digitek®. (# 273, pp. 1-2.) Defendants point out that the report does not mention Digitek®, or any other product. (# 273, p. 6.)

In reply, Plaintiffs assert that while they do not question counsel for the Actavis Defendants' statement that counsel did not become aware of Mr. Galea's assessment and report until several months after this category of documents was requested, this

"suggests a lack of effort by the Actavis Defendants to respond in earnest to Plaintiffs' discovery requests." (# 282, p. 2.) Thus, Plaintiffs continue to assert that the Actavis Defendants waived the self-critical analysis privilege. (# 282, p. 2.) Plaintiffs continue in their assertion that the assessment and report of Mr. Galea is highly relevant. Finally, they assert that "the available case law as discussed at length in Plaintiffs' motion clearly disfavors ... application [of the self-critical analysis privilege] under the present circumstances." (# 283, pp. 2-3.)

2. Deposition of Mr. Galea.

On December 9, 2009, Plaintiffs deposed Paul Galea, Director of Quality Assurance Operations for Actavis Totowa LLC. Mr. Galea testified that in October of 2007, he was transferred from Actavis, Limited in Malta to Actavis Totowa LLC for the purpose of conducting "an assessment and helping out in the ... harmonization of the group's corporate manual and that was basically the main reason." (# 265-4, p. 2.) Mr. Galea described harmonization as looking "at the various companies and see[ing] that they are working under the same umbrella." (# 265-4, p. 24.) Regarding the assessment, Mr. Galea testified that he went to Actavis Totowa LLC to make an assessment "[i]n general ... from a GMP perspective" at the request of the head of quality for Actavis Group.² (# 265-4,

² Mr. Galea testified that GMP, or "good manufacturing practices," are a "set of rules and guidances which direct you in the manufacturing and packaging and testing of your product. *** The objective is to manufacture a tablet which is good for human use." (# 265-4, p. 34.)

pp. 3, 14.) When questioned further about his activities at Actavis Totowa LLC, counsel for Actavis Defendants objected to many questions posed by Plaintiffs and in some cases, instructed Mr. Galea not to answer the question. (See i.e., # 265-4, p. 6.) In other instances, counsel allowed Mr. Galea to answer, but instructed him not to reveal any of the findings or substantive evaluations that he did. (# 265-4, p. 7.) In any event, Mr. Galea testified that he conducted an initial assessment from February 2 through 7 or 9, 2007, that his inspection included actual inspection and review of the quality control labs with Actavis Totowa LLC, and that he looked at logbooks. (# 265-4, pp. 6-7, 9.) Mr. Galea made other visits to Actavis Totowa LLC in March of 2007, May of 2007 and June to July of 2007. (# 265-4, p. 13.) Mr. Galea testified that his initial visit in February was for "an assessment," his March visit was part assessment, part harmonization, and his visits thereafter involved "look[ing] at harmonization." (# 265-4, pp. 13-14.) Mr. Galea testified that sometime after his February visit, he completed a report regarding his assessment and sent it to the quality systems department, "which takes care of internal audits for the group." (# 265-4, p. 17.) The report contained recommendations with respect to the GMP program for Actavis Totowa LLC. (# 265-4, p. 19.) Mr. Galea explained that the procedures of GMP as used by the quality group are not product specific; "[p]rocedures tell you how to perform an

operation" and "do not necessarily apply to a product." (# 265-4, pp. 26-27.)

3. Involvement of the FDA.

In the court's order entered on July 1, 2009 (PTO # 27), in which the court expanded the scope of discovery with respect to Little Falls product batches, the production of which immediately preceded production of Digitek® batches using any of the same equipment, the court summarized the activities of the FDA leading up to the recall of Digitek® in April of 2008:

In January, 2006, the Food and Drug Administration ("FDA") conducted an inspection of the Little Falls plant and, in August, 2006, issued a warning letter concerning the reporting and investigating of adverse drug events ("ADE"). [# 73 (Master Complaint)], ¶¶ 19-23, at 5-6. In July, 2006, FDA inspected the Little Falls plant and, in February, 2007, issued a revised warning letter concerning deviations from current good manufacturing practices, resulting in the adulteration of certain medications manufactured by Actavis Totowa, LLC. Id., ¶¶ 24-37, at 6-9. On April 25, 2008, FDA announced a Class I recall of all lots of Digitek® manufactured and marketed by named defendants "due to the possibility that tablets with double the appropriate thickness may contain twice the approved level of active ingredient. The existence of double strength tablets poses a risk of digitalis toxicity in patients with renal failure." Id., ¶¶ 38, at 9-10.

(# 150, pp. 1-2.)

4. Analysis.

The court finds that Plaintiffs' Motion should be granted. In discovery, Plaintiffs asked for "[a]ll documents or records relating to any internal audits conducted by the compliance division or any quality department in the last ten years at any of

the facilities used by Actavis Totowa LLC, including but not limited to the Little Falls Facility, the Taft Road Facility and the Riverview Facility.” (# 265-3, p. 5.) Plaintiffs also sought documents dealing with internal investigations related to Ditigek® conducted in the last ten years and documents related to any inspections conducted by Actavis HF or the Actavis HF compliance group. (# 265-3, p. 5.) The Actavis Defendants objected to the requests regarding “internal audits” as vague and confusing because Plaintiffs failed to define that term. (# 265-3, p. 6.) According to the Actavis Defendants, Plaintiffs never defined the term and, to date, have not formally requested a copy of Mr. Galea’s assessment report. Thus, according to the Actavis Defendants, the self-critical analysis has never been asserted or waived. (# 273, p. 5.)

Though the Actavis Defendants assert otherwise, Mr. Galea’s “assessment” and ensuing report following his February visit are responsive, at a minimum, to the discovery request seeking internal audits. The court disagrees with the Actavis Defendants’ assertion that the request seeking internal audits is vague. Mr. Galea’s assessment and resulting report should have been identified in response to this request for production, and if the Actavis Defendants believed it was subject to a privilege, identified the report in a privilege log. However, the court will accept counsel’s representation that they did not become aware of Mr. Galea’s work

in 2007 or his assessment report until Mr. Galea's pre-deposition interview in November of 2009, and did not receive the report until December of 2009. (# 273, p. 6.)

Turning to the issue of application of the self-critical analysis privilege, Rule 501 provides that

[e]xcept as otherwise required by the Constitution of the United States or provided by Act of Congress or in rules prescribed by the Supreme Court pursuant to statutory authority, the privilege of a witness, person, government, State, or political subdivision thereof shall be governed by the principles of the common law as they may be interpreted by the courts of the United States in the light of reason and experience. However, in civil actions and proceedings, with respect to an element of a claim or defense as to which State law supplies the rule of decision, the privilege of a witness, person, government, State, or political subdivision thereof shall be determined in accordance with State law.

Fed. R. Evid. 501.

Plaintiffs' Master Complaint alleges both State and Federal claims. (See # 73 (Master Complaint).) In "a case involving both federal and state law claims, the federal law of privilege applies." Virmani v. Novant Health Inc., 259 F.3d 284, 287 n.3 (4th Cir. 2001). Generally, the proponent of the privilege has the burden of proving its applicability. See United States v. (Under Seal), 748 F.2d 871, 876 (4th Cir. 1984) (The burden of persuasion on each of the elements of the attorney-client privilege is clearly upon the proponent.); United States v. Tedder, 801 F.2d 1437, 1441 (4th Cir. 1986) (The proponent of the attorney-client privilege had the burden of showing its applicability.); North Carolina Elec. Membership Corp. v. Carolina Power & Light, Co., 110 F.R.D. 511,

513 (M.D. N.C. 1986) (citing United States v. (Under Seal), 748 F.2d at 876).

In Etienne v. Mitre Corp., 146 F.R.D. 145, 146-47 (E.D. Va. 1993), the court observed that

Federal Rule of Evidence 501 generally leaves the area of privilege to the trial court's discretion. In enacting Rule 501, Congress clearly rejected the creation of specific privileges in favor of providing the courts with greater flexibility. See, Trammel v. United States, 445 U.S. 40, 47, 100 S. Ct. 906, 910, 63 L.Ed.2d 186 (1980) (stating that Rule 501 provides for development of privilege law on a "case-by-case basis"); S.Rep. No. 1277, 93rd Cong., 2nd Sess. 11 (1974), reprinted in 1974 U.S.C.C.A.N. 7051, 7059 ("[T]he recognition of a privilege based on a confidential relationship and other privileges should be determined on a case-by-case basis.")

(footnote omitted).

The Actavis Defendants concede that "[t]here is no Fourth Circuit authority expressly adopting or rejecting the privilege" (# 273, p. 8.) Indeed, since Bredice v. Doctor's Hosp., Inc., 50 F.R.D. 249, 250 (D. D.C. 1970), aff'd, 479 F.2d 920 (Table) (D.C. Cir. 1973), when the United States District Court for the District of Columbia held that a decedent's administratrix in a medical malpractice action could not obtain the minutes and reports of a medical staff meeting related to potential improvements in its procedures and treatments, "the privilege has remained 'largely undefined and not generally recognized by many authorities.'" Etienne, 146 F.R.D. at 147 (quoting Guardian Life Ins. Co. v. Service Corp. Int'l, Civ. A. No. 87-1280T, 1989 WL 3496, at * 3 (E.D. Pa. Jan. 17, 1989)); see also McDougal-Wilson v.

Goodyear Tire and Rubber Co., 232 F.R.D. 246, 250 (E.D. N.C. 2005) (noting that the privilege is of recent origin and one that is narrowly applied even in those jurisdictions where it is recognized); In re Air Crash at Charlotte, N.C. on July 2, 1994, 982 F. Supp. 1052, 1054 (D. S.C. 1995) (same).

As the Western District of Virginia recognized in 2005,

[a]llthough neither the Supreme Court nor the Fourth Circuit have expressly discredited this privilege, the Court also recognizes that the Supreme Court counsels strongly against the recognition of new privileges. See Jaffee v. Redmond, 518 U.S. 1, 116 S.Ct. 1923, 135 L.Ed.2d 337 (1996). **Further, the Court is not aware of any case in this Circuit both approving of this privilege and applying it to prevent disclosure of documents.** The Court, therefore, wearily and skeptically treads into this territory.

Deel v. Bank of America, N.A., 227 F.R.D. 456, 458 n.4 (W.D. Va. 2005) (emphasis added). In Deel, the court ultimately concluded that in the context of an action alleging violations of the Fair Labor Standards Act, defendant could not satisfy the elements of the self-critical analysis privilege, which was asserted with respect to documents compiled by the employer in connection with an audit of its job classifications. Id. at 459.

This court also was unable to locate a court within the Fourth Circuit approving the privilege and applying it to prevent disclosure of documents or other discovery. Plaintiffs further state in their brief that a number of other circuits, including the Second, Third, Fifth, Seventh, Eighth, Ninth, Tenth, Eleventh, and the D.C. Circuits have either "rejected, or shown reluctance to

recognize, the self-critical analysis privilege" (# 265-2, pp. 10-11), an assertion not challenged by the Actavis Defendants.

Even if the court were to acknowledge and accept the privilege, which it does not, the Actavis Defendants have not shown that it applies to Mr. Galea's report. The self-critical analysis requires that

(1) information contained in the document result from an internal investigation conducted to evaluate or improve a party's procedures or products; (2) the party originally had intended that the information remain confidential and demonstrate a strong interest in preserving the free flow of the type of information sought; and (3) the information contained in the document be of a type whose flow would be curtailed if discovery were allowed.

Deel, 227 F.R.D. at 459 (citing Etienne, 146 F.R.D. at 147).

The court cannot conclude that the information obtained during Mr. Galea's assessment and report would be of the type whose flow would be curtailed if discovery of the assessment and report were allowed. Mr. Galea testified that he was sent to Actavis Totowa to conduct an assessment "in general ... from a GMP perspective" and to harmonize the group's corporate manual so that the various companies were working under the same umbrella. (# 265-4, pp. 2, 24.) He conducted his work at the request of the head of quality for Actavis Group and while there, inspected and reviewed the quality control labs and looked at logbooks. (# 265-4, pp. 3, 6-7, 9, 14.) He ultimately sent his report to the quality systems department, "which takes care of internal audits for the group."

(# 265-4, p. 17.)

Pharmaceutical companies such as the Actavis Defendants are stringently regulated by the federal government and highly competitive with one another. The court is hard pressed to believe further audits or assessments of this nature would not be conducted if such information were disclosed in this litigation. In fact, such audits seem essential to the success of the Actavis Defendants' business.

As the court in In re Air Crash at Charlotte, N.C. observed, to the extent such a privilege is even recognized, "information otherwise subject to the privilege 'must be disclosed whenever it is material to the adversary's case, and where the information therein cannot be obtained through alternative sources.'" In re Air Crash at Charlotte, N.C., 982 F. Supp. at 1055 (quoting Federal Rules of Evidence Manual, Vol. 2, p. 637 (6th ed. 1994)).

Even if the report prepared by Mr. Galea does not mention Digitek® or any other drug by name, as the Actavis Defendants represent, to the extent it deals with Actavis Totowa's GMPs around the time of the FDA's warning letters and ultimate recall of Digitek® such information is highly relevant, and in the absence of an applicable privilege or other reason to avoid production, must be turned over to Plaintiffs.

Accordingly, it is hereby **ORDERED** that Plaintiffs' Motion to Compel Documents and Deposition Testimony is **GRANTED**. It is

further hereby **ORDERED** that the Actavis Defendants produce Mr. Galea's report on or before **February 24, 2010**, and work with Plaintiffs to reschedule Mr. Galea's deposition. The court finds that the Actavis Defendants' position in opposing Plaintiffs' Motion was not substantially justified pursuant to Rule 37(a)(3)(B)(i) and 37(a)(5)(A), and, as a result, Plaintiffs may submit an Affidavit of their fees and expenses related to filing and replying to the Motion and conducting Mr. Galea's second deposition within seven (7) days of Mr. Galea's deposition. The Actavis Defendants may respond within seven (7) of Plaintiffs' filing of their Affidavit if they oppose the Affidavit and should indicate who, as between counsel and client, is responsible for the actions that resulted in Plaintiffs' Motion.

Finally, the court reminds the parties that pursuant to PTO # 22, "[d]isputes arising during depositions that cannot be resolved by agreement and that, if not immediately resolved, will ... require rescheduling of the deposition, or might result in the need to conduct a supplemental deposition, shall be presented to Judge Goodwin or Magistrate Judge Stanley by telephone." (# 122, p. 9.) The parties could have avoided a time consuming and expensive discovery dispute had they followed this provision in PTO # 22.

Motion to Seal

Plaintiffs seek an order filing Exhibit B to its Motion to Compel under seal because pages 43, 83, 155 and 172 of Paul Galea's deposition transcript have been designated by the Actavis Defendants as confidential. While Plaintiffs disagree with the Actavis Defendants' assertion that these documents are confidential pursuant to PTO # 12, Plaintiffs filed the instant Motion to comply with PTO # 12.

Defendants did not respond to this Motion.

Accordingly, it is hereby **ORDERED** that Plaintiffs' Motion for Leave to File Plaintiffs' Motion to Compel Documents and Deposition Testimony under seal is **DENIED**.

The Clerk is directed to file this Order in 2:08-md-1968 which shall apply to each member Digitek®-related case previously transferred to, removed to, or filed in this district, which includes counsel in all member cases up to and including civil action number 2:10-cv-00132. In cases subsequently filed in this district, a copy of the most recent pretrial order will be provided by the Clerk to counsel appearing in each new action at the time of filing of the complaint. In cases subsequently removed or transferred to this court, a copy of the most recent pretrial order will be provided by the Clerk to counsel appearing in each new action upon removal or transfer. It shall be the responsibility of the parties to review and abide by all pretrial orders previously

entered by the court. The orders may be accessed through the CM/ECF system or the court's website at www.wvsc.uscourts.gov.

ENTER: February 10, 2010



Mary E. Stanley
United States Magistrate Judge